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UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: A. Farah

Art Unit: 3739

Re: Application of:

Luis NAVARRO, et al.

Serial No.:

09/374,280

Filed:

August 13, 1999

For:

TREATMENT OF LARGE VEINS

AMENDMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

March 15, 2001

Sir:

In response to the Office Action dated November 15, 2000, entry and consideration of the following amendments and remarks are respectfully requested.

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I hereby certify that this correspondence and/or fee is being deposited with the United States Postal Service as first class mail in an envelope addressed to "Assistant Commissioner for Patents Washington, D.C. 20231" on March 15, 2001 STEINBERG & RASKIN, P.C.

BY:

*Gyrette M. Pharo*

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**IN THE CLAIMS:**

Please amend the claims as follows:

1. (Amended) A blood vessel treatment device comprising:

means adapted for insertion into a blood vessel; and

means[,] adapted for intraluminal contact with a wall of [a] said blood vessel, for emitting laser energy to cause a decrease in the diameter of said blood vessel.

Please add new claim 21 as follows:

21. A method of treating a blood vessel using laser energy, comprising the steps of:

inserting means for emitting laser energy into the blood vessel at a puncture site, wherein said emitting means has a laser emitting section;

placing said laser emitting section of said emitting means into intraluminal contact with the blood vessel at a treatment site;

emptying the blood vessel; and

emitting said laser energy into the blood vessel through said laser emitting section of said emitting means, thereby decreasing the diameter of said blood vessel.

REMARKS

Reconsideration of the present application, as amended, is respectfully requested.

**I. Status of the Claims**

Claims 1-21 are now pending, claim 1 having been amended and new claim 21 having been added. New independent claim 21 includes the subject matter of allowable claim 10 and base claim 9. Thus it is submitted that independent claim 21 is allowable.

**II. Rejections Under 35 U.S.C. §112**

Claims 1-8 were rejected under 35 U.S.C. §112, first paragraph, on the grounds that the claim recited a single means and is therefore subject to an undue breadth rejection.

Independent claim 1 has been amended herein to recite two "means". Specifically claim 1 has been amended to recite that the claimed device comprises "means adapted for insertion into a blood vessel; and means adapted for intraluminal contact with a wall of said blood vessel, for emitting laser energy to cause a decrease in the diameter of said blood vessel". Accordingly, it is submitted that the Examiner's rejection of claim 1 under 35 U.S.C. §112, first paragraph has been overcome and should be withdrawn.

### III. Rejection Under 35 U.S.C. §102 (b)

Claims 1-4, 7-9, 12, 13, 18 and 19 were rejected under 35 U.S.C. 102(b) as being clearly anticipated by Trelles U.S. Patent No. 5,531,739. The Examiner's rejection is respectfully traversed.

Independent claim 1 recites a blood vessel treatment device which includes "means adapted for *intraluminal* contact with a wall of said blood vessel, for emitting laser energy to cause a decrease in the diameter of said blood vessel". (emphasis added) Thus the device according to the claimed intention, as shown in Figure 4B, is adapted to be inserted within the vein to be treated so that contact with the blood vessel wall is made *from within the vein* (i.e. intraluminal contact).

It is respectfully submitted that a close review of the Trelles reference reveals that it fails to teach any device which is adapted to make "*intraluminal* contact with a wall of a blood vessel" in the manner of the claimed invention. Trelles discloses a method in which a probe is advanced to a position *underneath* the vessel to be treated. Once in this position the vein is irradiated from a position *exterior* of the vein. This is clearly depicted in Fig. 2 of the Trelles patent. In view of the forgoing it is clear that Trelles fails to disclose a device which is adapted to make intraluminal contact with a wall of a blood vessel in the manner of the claimed invention and therefore cannot anticipate the device recited in claim 1.

Claims 2-4 and 7-8 depend directly from claim 1 and thereby incorporate all of the features and limitations recited in claim 1. Therefore it is respectfully submitted that Trelles also fails to anticipate the invention recited in these claims.

Independent claim 9 recites a method which includes the step of "placing said laser emitting section into *intraluminal* contact with the blood vessel at a treatment side". As discussed above with respect to claim 1 Trelles fails to disclose a method wherein a laser emitting section of a device is placed into intraluminal contact with a blood vessel. Rather, as discussed above, Trelles discloses a method wherein the vessel is treated from a exterior position relative to the vessel. Accordingly it is submitted that Trelles cannot anticipate the claimed invention according to independent claim 9. Claims 12, 13 and 18 and 19 depend from claim 9 and therefore incorporate all of the limitations and features thereof. Accordingly it is submitted that Trelles also fails to anticipate claims 12, 13, 18 and 19.

The Examiner further rejected claims 1, 4, 9, 11, 17 and 19 under 35 U.S.C. 102(b) as being anticipated by Goldman U.S. Pat. No. 4,564,011. The Examiner's rejection is respectfully traversed.

Independent claim 1 recites a blood vessel treatment device including means "adapted for *intraluminal contact* with a wall of a blood vessel, for emitting laser energy to cause *a decrease in the diameter of said blood vessel*". (emphasis added) Thus the device according to the claimed invention is arranged inside the vein to be treated and then the laser is directed against a

wall of the vein to thereby cause fibrosis of the vein leading to a decrease in the diameter of the vein. (See specification p. 8, lines 16-28). It is respectfully submitted that a close review of the Goldman reference reveals that the device disclosed therein is not adapted to deliver energy *to the vein wall in an intraluminal manner to thereby decrease the diameter of the vein.*

Goldman discloses a laser optic device 11 which includes a needle 27. As shown in Fig. 3 and discussed at column 3, line 44 through column 4, line 32 the needle may be inserted within the vein. However as discussed in the specification of Goldman the laser energy is not directed into the wall of the blood vessel but rather is *used to create a blood clot in the vessel.* Accordingly, unlike the claimed invention, there is no intraluminal contact with the blood vessel nor any delivery of laser energy to the vessel wall to thereby cause a decrease in the size of the vessel. Rather in Goldman a blood clot is generated to thereby cause a stoppage of flow in the vessel which in turn causes a decrease in the diameter of the vessel.

In another application of the device disclosed in Goldman, discussed at column 4, lines 33-66, the needle 27 is inserted in a position *near* the blood vessel to be treated. The tissue *near* the vessel is then subjected to laser energy to cause this tissue to scar. This scar tissue exerts a pressure on the nearby vessel and "effectively stops the flow of blood therethrough". Again however there is no contact with the vessel wall and certainly no intraluminal contact with the blood vessel wall.

In view of the above it is submitted that Goldman fails to teach the device recited in claim

1. Claim 4 depends from claim 1 and therefore includes all of the limitations and features recited therein. Accordingly it is submitted that Goldman also fails to anticipate the invention recited in claim 4.

Independent claim 9 recites a method in which laser emitting means is placed in *intraluminal contact* with a blood vessel and laser energy is directed *into the blood vessel wall* to thereby decrease the diameter of the vessel. As discussed above with respect to the claim 1 the Goldman reference fails to teach any such method. Accordingly it is submitted that Goldman fails to anticipate the claimed invention according to claim 9. Claims 10-11, 17 and 19 depend from claim 9 and thus include all of the features and limitations recited therein thus it is submitted that Goldman also fails to anticipate claims 10-11, 17 and 19.

#### IV. Rejection Under 35 U.S.C. §103 (a)

The Examiner further rejected claims 5, 6, 14-16 and 20 under 35 U.S.C. §103(a) as being unpatentable over Trelles U.S. Pat. No. 5,531,739 in view of Gay, Jr. U.S. Pat. No. 5,334,207.

It is submitted that Gay, Jr. fails to overcome the deficiencies of the Trelles reference discussed above. That is, it is submitted that Gay, Jr. fails to disclose a device including means adapted for intraluminal contact with a wall of a blood vessel for emitting laser energy to cause a decrease in diameter of said blood vessel. Likewise it is submitted that Gay, Jr. fails to disclose a method which includes the steps of placing emitting means in intraluminal contact with a blood vessel and emitting laser energy to decrease the diameter of said blood vessel. Since Gay, Jr. fails

to overcome the deficiencies of Trelles it is submitted that it cannot be combined therewith to thereby render the claimed invention obvious.


A one-month extension of time extending the time for response from February 15, 2001 until March 15, 2001 is enclosed herewith together with the appropriate extension fee. The fee for the additional claim is also enclosed. If it is determined that any other fee is required, the Patent and Trademark Office is specifically authorized to charge such fee to Deposit Account No. 50-0518 in the name of Steinberg & Raskin, P.C.

According to currently recommended Patent Office policy, the Examiner is specifically authorized to contact the undersigned in the event that a telephonic interview would advance the prosecution of this application.

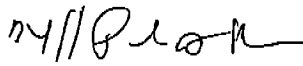
An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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